Exhibit K

Not Reported in F.Supp.2d, 1999 WL 509471 (S.D.N.Y.), 1999-2 Trade Cases P 72,603
(Cite as: Not Reported in F.Supp.2d)

Zeneca Inc. v. Eli Lilly and Co.
S.D.N.Y.,1999.

United States District Court, S.D. New York.
ZENECA INC., Plaintiff, and
BARR LABORATORIES, INC.,
Plaintiff-Intervenor,
v.
ELI LILLY AND COMPANY, Defendant.
No. 99 CIV. 1452(JGK).

July 19, 1999.

Harold P. Weinberger, Esq., Kramer Levin Naftalis & Frankel LLP, New York, for the Plaintiff.
Michael K. Atkinson, Esq., Winston & Strawn, Washington, D.C., Daniel Murdock, Esq., Winston & Strawn, New York, for the Plaintiff Intervenor.
Nina M. Gussack, Esq., Pepper Hamilton LLP, Philadelphia, PA, for the Defendant.

OPINION AND ORDER

KOELTL, District J.

***1** The plaintiff, Zeneca Inc. ("Zeneca") [FN1], and plaintiff-intervenor Barr Laboratories, Inc. ("Barr"), have sued the defendant, Eli Lilly and Company (" Eli Lilly"), under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), and under the common law and statutory law of New York that prohibits unfair competition and deceptive trade practices. Zeneca is the manufacturer of the breast cancer drug tamoxifen citrate (hereinafter "tamoxifen citrate" or " tamoxifen"), which Zeneca markets and sells under the name Nolvadex. Barr distributes generic tamoxifen citrate pursuant to a licensing agreement with Zeneca. Tamoxifen citrate has been approved by the Food and Drug Administration ("FDA") for the reduction of the incidence of breast cancer in women at high risk of developing the disease.

FN1. Since this action was filed, Zeneca Inc. has merged with a pharmaceutical company called Astra. The merged entity is now called AstraZeneca Inc. Tr. at 2.

Eli Lilly manufactures and sells the drug raloxifene hydrochloride (hereinafter "raloxifene") under the name Evista. Evista has been approved by the FDA for the prevention of osteoporosis in postmenopausal women. Zeneca and Barr allege that Eli Lilly is making three false claims about Evista: 1) that Evista has been proven to reduce the risk of breast cancer, 2) that Evista is comparable or superior to tamoxifen citrate for the prevention of breast cancer, and 3) that Evista has been indicated or approved by the FDA for the prevention of breast cancer. Defendant Eli Lilly argues that it has not made the second or third claims alleged. As to the first claim, the defendant argues that such a claim is not false because Evista has been proven to reduce the risk of breast cancer.

Zeneca and Barr have moved for a preliminary injunction. Following extensive expedited discovery, the Court held a five-day evidentiary hearing. As explained in detail below in the Court's Findings of Fact and Conclusions of Law, Eli Lilly has been promoting Evista with the claim that it has been established that it reduces the risk of breast cancer. That claim is based on the results of a significant clinical trial-the Multiple Outcomes of Raloxifene Evaluation ("MORE") study-but the results of that trial do not prove that it has been established or proven that Evista reduces the risk of breast cancer. Further research is necessary to support the claim, and the FDA has specifically required Eli Lilly to include in the label for Evista, while discussing the results of the MORE trial, that " [t]he effectiveness of raloxifene in reducing the risk of breast cancer has not yet been established."Def.'s Exh. H (Evista Package Insert Revised as of Dec. 2, 1998) at 8. Hence, it is literally false for Eli Lilly to promote Evista with the claim that it has been established or proven that Evista reduces the risk of breast cancer. It is important in the public interest

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that the results of the MORE trial, as discussed below, be disseminated so that doctors and public health professionals can assess and understand the results of that study. It is also important, however, that the results of that study be truthfully disseminated and that false claims not be made, because false claims will not only hurt competitors who are marketing a drug that has been established to reduce the risk of breast cancer, but such false claims will also harm the public interest in assuring that truthful information about highly significant drugs is disseminated.

***2** As a preliminary matter, during the evidentiary hearing the parties raised a number of hearsay objections. The Court received the evidence, including hearsay evidence such as affidavits, subject to a motion to strike. In reaching the Findings of Fact and Conclusions of Law, the Court has considered the hearsay objections raised by all parties. The Court has concluded that the objections do not warrant exclusion of the evidence. The Court has, however, carefully considered the reliability of all the disputed evidence and will separately discuss the evidence as to which objections were made. The strict rules of evidence do not apply to a hearing on a motion for a preliminary injunction. *See, e.g., Securities and Exch. Comm'n v. Cherif,* 933 F.2d 403, 412 n.8 (7th Cir.1991), *cert. denied,*502 U.S. 1071 (1992); *Asseo v. Pan American Grain Co.,* 805 F.2d 23, 25-26 (1st Cir.1986); *Commodity Futures Trading Comm'n v. American Metal Exch. Corp.,* 693 F.Supp. 168, 173 (D.N.J.1988); *Delman Fabrics Inc. v. Holland Fabrics, Inc.,* 84 Civ. 2512, 1984 WL 367, at *5 (S.D.N.Y. May 17, 1984). The Court has, nevertheless, applied the Federal Rules of Evidence in determining the weight to be accorded the evidence that was introduced and has also assessed whether the evidence would be admissible under the Federal Rules of Evidence.

The defendant objects first to the admissibility of the "call notes" that were written by Eli Lilly sales representatives about their meetings with and " detailing" of doctors concerning Evista. The defendant argues that the call notes are inadmissible hearsay and do not meet any of the exceptions to the hearsay rule.

As an initial matter, as noted above, the Court may consider hearsay evidence in a preliminary injunction hearing. In any event, the call notes satisfy the business records exception to the hearsay rule. *See*Fed.R.Evid. 803(6). The testimony of Newt Crenshaw, Eli Lilly's Vice President of U.S. Sales, established that sales representatives are required to submit call notes in the course of their duties, that they are trained in how to make call notes, and that the call notes are required to be typed up as soon as possible after each visit with a doctor-usually the same day as the visit itself. Moreover, the call notes are intended to be accurate because sales representatives rely on the call notes when planning future meetings with doctors. The call notes are also backed up on a central computer system. Tr. at 152-63 (Crenshaw); *see also* Tr. at 852-53, 875-78 (Torres) (indicating that call notes are like a "diary" and that they are used by sales representatives and their partners to record accurate information). It is plain that the notes are made at or near the time of the meeting with the doctors by a sales representative with knowledge of the meeting, that the call notes are kept in the ordinary course of Eli Lilly's business, and that it was the regular practice of Eli Lilly's sales representatives to write and keep call notes. Thus the call notes are admissible under Rule 803(6).*See, e.g., United States v. Goodchild,* 25 F.3d 55, 62 (1st Cir.1994).

***3** The call notes are also admissible as admissions under Federal Rule of Evidence 801(d)(2)(D). To be admitted under Rule 801(d)(2)(D), a party must demonstrate only "(1) the existence of the agency relationship, (2) that the statement was made during the course of the relationship, and (3) that it relates to a matter within the scope of the agency."*Pappas v. Middle Earth Condominium Assoc.,* 963 F.2d 534, 537 (2d Cir.1992). In this case, the plaintiff has demonstrated that an agency relationship existed between the sales representatives and Eli Lilly, that the statements in the call notes were made during the course of that relationship, and that the call notes concerned a matter within the scope of the agency relationship-namely the promotion and detailing of Evista. Thus the call notes are admissible under Rule 801(d)(2)(D).

Moreover, the probative value of the notes is not

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outweighed by any danger of unfair prejudice. The notes are highly probative of what the representatives said, which is an important issue in the case, they are not inflammatory, and they do not present a situation where the Court is being asked to consider them for an improper purpose. There is no basis for arguing they should be excluded under Federal Rule of Evidence 403.

The defendant next moves to exclude certain FDA documents on hearsay grounds. But hearsay evidence is admissible in a hearing on a preliminary injunction. Further, the documents are not hearsay to the extent that they are not offered for their truth. Here, the plaintiff seeks to admit the FDA documents for the fact of what the FDA said to Eli Lilly about Evista, the results of the MORE study, and the meaning of the language in the Evista label. The documents are relevant to Eli Lilly's contention concerning the FDA's interpretation of the MORE study and the meaning of the language on Evista's label stating that "[t]he effectiveness of raloxifene in reducing the risk of breast cancer has not yet been established."Thus the documents are admissible as non-hearsay.

The FDA documents-in particular the minutes of the January 1999 and May 1999 meetings-are also admissible under the exception to the hearsay rule for public records that set forth "factual findings resulting from an investigation made pursuant to authority granted by law, unless the sources of information or other circumstances indicate lack of trustworthiness."Fed.R.Evid. 803(8)(c). The Meeting Minutes sought to be admitted contain factual findings by the FDA concerning Evista's efficacy for breast cancer prevention. The Minutes were the result of a timely review. There is no dispute that the FDA has the authority to and routinely does evaluate clinical data submitted by pharmaceutical companies and that the FDA's Division of Oncology Drug Products specifically performs this function with respect to cancer drugs. Tr. at 428-29 (Carlson); Tr. at 740-41 (Cummings). Moreover, the FDA's investigators have technical skill and expertise and were unbiased. In addition, other factors confirm the reliability of the documents. For example, Eli Lilly was given the opportunity to review the Meeting Minutes and to correct any errors in them. Tr. at 1117-18 (Dere); Def.'s Exh. K-9 (stating in cover letter to Meeting Minutes from May 11, 1999 that "[t]hese minutes are the official minutes of the meeting. You are responsible for notifying us of any significant differences in understanding you have regarding the meeting outcomes"). Thus the FDA documents, including the Meeting Minutes, are trustworthy and admissible.

***4** The fact that the Minutes are the FDA's non-final factual findings does not render the reports untrustworthy and inadmissible. *See Reynolds v. Giuliani,* 98 Civ. 8877, 1999 WL 33027, at *2 (S.D.N.Y. Jan. 21, 1999); *Meriwether v. Coughlin,* 879 F.2d 1037, 1039 (2d Cir.1989) (noting admission of a page of an interim report). The *Pullman* case cited by the defendant is not to the contrary because it affirmed the exclusion of a non-final report by a government agency not merely because the report was an "interim" report but also because the report, unlike the FDA minutes, " expressly declined to state a conclusion on the most significant safety question" at issue in that case. *See City of New York v. Pullman Inc.,* 662 F.2d 910, 914-15 (2d Cir.1981). In sum, the defendant has not demonstrated that the FDA Meeting Minutes are untrustworthy and thus the motion to exclude them is denied. The defendant was, of course, permitted to introduce evidence that goes to the weight to be given to the factual conclusions stated in the Meeting Minutes and that evidence has been considered by the Court.

Finally, the Court will consider the doctors' affidavits that have been submitted by the defendant. These affidavits attempt to contradict some of the call notes. Def.'s Exhs. T-4 through R-5. The strict rules of evidence do not apply in a preliminary injunction hearing. However, the Court is mindful of the fact that there is a preference for live testimony when the Court is called on to resolve disputed issues of fact. *See, e.g., Davis v. New York City Housing Auth.,* 166 F.3d 432, 437-38 (2d Cir.1999) ("When a factual issue is disputed, oral testimony is preferable to affidavits."); *Fox Broadcasting Co. v. Fox Broadcasting Co.,* 86-4989, 1986 WL 11445, at *1 (E.D.Pa. Oct. 9, 1986) (determining that the Court would consider

affidavits in deciding a motion for a preliminary injunction even though the authors of the affidavits were not available to be cross-examined, but noting that the Court would be aware of that objection "in determining the evidentiary weight of any relevant affidavit"); *cf. Securities and Exch. Comm'n v. Petrofunds, Inc.,* 414 F.Supp. 1191, 1196 (S.D.N.Y.1976) (noting that when district judges are asked to award preliminary relief, they are "not to resolve a factual dispute on affidavits or depositions for then (they are) merely showing a preference for one piece of paper to another") (internal citation omitted) (Weinfeld, J.). Thus although the Court will consider the doctors' affidavits, the affidavits are necessarily of less weight than the live testimony of witnesses who were available and subject to cross-examination at the hearing.

The Court now makes the following findings of fact and reaches the following conclusions of law.

I.

FINDINGS OF FACT

A. The Parties

1. Plaintiff Zeneca is a Delaware corporation with its principal place of business in Wilmington, Delaware. The company researches, develops, and produces medicines. (Compl. ¶ 6; Ans. ¶ 6.) Zeneca manufactures and sells a breast cancer drug called Nolvadex (tamoxifen citrate).Nolvadex has been approved by the FDA for the reduction of the incidence of breast cancer in women at high risk of developing the disease. Pl.'s Exh. 3 (Nolvadex label) at p. 13.

***5** 2. Defendant Eli Lilly is an Indiana corporation with its principal place of business in Indianapolis, Indiana. Eli Lilly is a global pharmaceutical corporation that, like Zeneca, researches, develops, and markets medicines for use in a variety of therapeutic areas. Eli Lilly advertises, distributes, and sells its pharmaceutical products throughout the United States. (Compl. ¶ 7; Ans. ¶ 7.)

3. Plaintiff-intervenor Barr is a New York corporation with its principal place of business in Pomona, New York. Pursuant to a Distribution and Supply Agreement between Barr and Zeneca, Barr purchases from Zeneca and then distributes generic tamoxifen citrate under its own name. Tamoxifen citrate accounts for over 60% of Barr's net sales. Barr also markets two hormone replacement drugs for use in the treatment of osteoporosis, which compete directly with Eli Lilly's osteoporosis drug Evista. (Barr Compl. ¶ 8; Tr. at 548, 552-53 (Sawyer)).[FN2]

FN2. Barr moved to intervene approximately one month after Zeneca commenced this action. On May 4, 1999, the Court granted Barr's motion pursuant to Federal Rule of Civil Procedure 24(a)(2) and (b)(2).*See* Order dated May 4, 1999. Barr did not participate in expedited discovery but did attend and offer testimony at the hearing on the preliminary injunction.

B. Zeneca's breast cancer drug Nolvadex

4. In the 1970s, scientists at Zeneca developed a synthetic hormone "antagonist" called tamoxifen citrate, which was shown to have significant " anti-estrogenic" properties. Tamoxifen "antagonizes, " or counteracts or neutralizes, the cancer-promoting effects of estrogen in the breast by binding itself to the estrogen receptor in a cancerous cell. The presence of an anti-estrogen such as tamoxifen prevents estrogen from binding to the receptor, which in turn affects tumor growth. Tamoxifen has since been used, either in addition to or in lieu of more drastic and invasive forms of therapy, to treat both early and advanced-stage breast cancer and to prevent recurrence. Since it was first discovered nearly thirty years ago, tamoxifen has become the most widely prescribed treatment for breast cancer. Tr. at 42, 46-47 (Anson); Tr. at 299-301 (Lewis).

5. Zeneca markets tamoxifen under the brand name Nolvadex. Nolvadex is one of Zeneca's most successful and widely-prescribed products.

Nolvadex was originally approved by the FDA for the treatment of advanced breast cancer in 1978. It was later approved for other uses, including early stage adjuvant treatment, this is, treatment after the primary treatment for breast cancer, such as surgery. Tr. at 42, 47 (Anson); Tr. at 299-302 (Lewis).

6. Beginning in 1992, the National Cancer Institute (NCI) sponsored a clinical trial, conducted by the National Surgical Adjuvant Breast and Bowel Project (NSABP), to determine whether the use of tamoxifen could play a role in reducing the incidence of breast cancer in healthy women at high risk of developing the disease. This Breast Cancer Prevention Trial ("BCPT") enrolled more than 13,000 pre- and post-menopausal women at 131 different clinical sites. Tr. at 49 (Anson); Tr. at 306-08 (Lewis); Tr. at 440 (Carlson).

7. All the women recruited for the study were determined to be at high risk for developing breast cancer. Each woman qualifying for the study had to satisfy at least one of the following three enrollment criteria: (i) a history of lobular carcinoma in situ-benign breast tumors which are a known precursor to invasive or metastatic breast cancer, (ii) a score of 1.67 or higher on a breast cancer risk assessment model called the GAIL model, [FN3] and/or (iii) an age of 60 or older. Thirty percent of the patient population in the BCPT qualified based on the age criteria alone. The remainder fell into the other two risk categories. Tr. at 306-10 (Lewis).

FN3. The GAIL risk assessment model is a mathematical formula used to predict a woman's chances of developing breast cancer based on all known risk factors, including age, family history of breast cancer, age at onset of menstruation, age at first live birth, and number of benign breast biopsies. Tr. at 298-99 (Lewis); Tr. at 417 (Carlson).

***6** 8. The BCPT study demonstrated that the ongoing use of tamoxifen citrate by women at high risk of developing breast cancer reduced the incidence of invasive breast cancer by 49 percent. The results were so positive that NCI discontinued the study in March of 1998 to allow all high-risk women-including those in the placebo arm of the study-to benefit from its findings. Tr. at 49-50 (Anson); Tr. at 310-12 (Lewis).

9. In April 1998 Zeneca submitted a supplemental New Drug Application ("sDNA") to the FDA seeking approval of tamoxifen for use in reducing the incidence of breast cancer. Based upon the results of the Breast Cancer Prevention Trial, on October 29, 1998 the FDA, after an expedited review, approved tamoxifen for the reduction of the incidence of breast cancer in both pre- and postmenopausal women at high risk of developing the disease. Tr. at 47-49 (Anson); Tr. at 314-15 (Lewis); Pl.'s Exh. 3 (Nolvadex Label) at p. 13.

10. In the period between the conclusion of the BCPT trial and the FDA's approval of tamoxifen for the reduction of the risk of breast cancer, Zeneca devoted substantial time, energy, and resources to developing a marketing plan for tamoxifen's new indication. According to Lisa Anson, Zeneca's Business Development Manager for Oncology, the new indication for tamoxifen was viewed as a "very significant opportunity" for Zeneca-a potential " blockbuster drug." Tr. at 51-52 (Anson). Ms. Anson also highlighted the difficulties facing Zeneca in marketing tamoxifen for breast cancer risk reduction because of the fact that "nobody has ever had a drug in the area of prevention" and "there [was] no ... market for risk reduction or prevention." Tr. at 52 (Anson). Zeneca thus had to create the market from scratch. Tr. at 51-53, 100 (Anson).

11. Shortly after FDA approval, in early November 1998 Zeneca began promoting tamoxifen for its new indication for the reduction of the risk of breast cancer. Tr. at 53 (Anson).

12. Over time, researchers have discovered that Nolvadex is associated with an increase in the risk of uterine cancer. This increased risk was not discovered until about ten years after tamoxifen was approved in the United States. Tr. at 303-05, 364 (Lewis).

C. Eli Lilly's osteoporosis drug Evista

13. One of Eli Lilly's products in the field of women's health is an osteoporosis drug called Evista

. Evista, which contains the active ingredient raloxifene hydrochloride, was first approved by the FDA in December 1997, solely for the prevention of osteoporosis in postmenopausal women. Tr. at 54 (Anson); Tr. at 317 (Lewis).

14. Evista is an important product for Eli Lilly. At least during the period right after launch, however, sales of Evista were disappointing. Tr. at 855 (Torres). Eli Lilly has since revised its Evista sales projections downward. Tr. at 856-57 (Torres).

15. While breast cancer is often associated with a high cumulative exposure to estrogen, osteoporosis afflicts women at the opposite end of the hormonal spectrum-those with reduced levels of estrogen. Estrogen acts on the bone to maintain bone density and thereby prevent osteoporosis. This may explain why postmenopausal women, who have less circulating estrogen, become increasingly vulnerable to osteoporosis. Tr. at 720 (Cummings); Tr. at 337-38 (Lewis); Tr. at 456-57 (Carlson).

***7** 16. Raloxifene, like tamoxifen, has been shown to have both estrogenic and anti-estrogenic properties. Tr. at 317-18 (Lewis). However, raloxifene is structurally different from tamoxifen. Tr. at 317-19 (Lewis).

17. In the mid-1990s, Eli Lilly scientists began a series of ten osteoporosis studies, one of which was titled "Multiple Outcomes of Raloxifene Evaluation " or "MORE." There is no dispute that the results from nine of these studies, even when combined, did not demonstrate that raloxifene decreases the incidence of newly diagnosed breast cancer. Tr. at 655 (Cummings); Tr. at 905-06 (Eckert); Tr. at 1125 (Dere); Lippman Dep. Tr. at 155-56.

18. The MORE study itself was a randomized, double-blind, placebo-controlled, multicenter clinical trial. The women in the study were randomly assigned to be given either raloxifene or a placebo, and neither they nor their doctors knew whether they were taking raloxifene or a placebo. Tr. at 608-09, 622 (Cummings); Pl.'s Ex. 37 (Clinical Study Main Report for the MORE study) at EV 2718 1545. The MORE study was designed to examine the outcomes of exposure to raloxifene and to gather the data necessary to secure an indication for Evista for the prevention of postmenopausal osteoporosis. Tr. at 618-19 (Cummings).

19. As discussed below, Eli Lilly has predicated its claim that Evista has been proven to reduce the incidence of breast cancer on the results of the MORE study. As of the date the study was terminated in early 1999, a total of forty cases of invasive breast cancer were reported among MORE study participants, 27 for the patients taking placebo and 13 for the nearly twice as many patients taking raloxifene. Tr. at 406-10 (Carlson); Def.'s Exh. L-9 ("The Effect of Raloxifene on Risk of Breast Cancer in Postmenopausal Women,"*The Journal of the American Medical Association ("JAMA"),* June 16, 1999) [FN4] at 2192. The results of the MORE study are discussed in greater detail below. Eli Lilly also plans to participate in a five-year comparative trial titled Study of Tamoxifen and Raloxifene ("STAR"), sponsored by NCI/NSABP, which will test the potential efficacy of Evista against the proven efficacy of tamoxifen in reducing the risk of breast cancer in postmenopausal women. Enrollment in STAR has just begun and the study likely will not be completed for at least five years. Tr. at 322 (Lewis); Pl.'s Exh. 34 (NSABP Protocol P-2 Study of Tamoxifen and Raloxifene (STAR) for the Prevention of Breast Cancer) at Z 15096.

FN4. The Journal of the American Medical Association, or "JAMA," is a prestigious medical journal in the United States. Lippman Dep. Tr. at 45.

D. Eli Lilly's promotional claims for Evista

20. Although Evista is an osteoporosis drug, Eli Lilly planned to market Evista for breast cancer prevention. Eli Lilly's market strategy documents and business plans contain numerous references to Evista's long-term "value proposition" and brand strategy that "Evista is the only single agent proven to safely protect women after menopause against three of the most serious threats to their health and independence: osteoporosis, breast cancer, and cardiovascular disease."Pl.'s Exh. 9 at EV 2014-1599; Pl.'s Exhs. 11 & 67. Eli Lilly witnesses have also described Evista's "competitive advantage, " at least over the long term, as protecting against the risk of breast cancer. Tr. at 217-19 (Torres).

***8** 21. Eli Lilly's internal documents also reflect the

company's understanding, based on market research it commissioned, that if Eli Lilly could make a breast cancer prevention claim for Evista, it would have a substantial impact on physicians and differentiate Evista from competitors. Tr. at 217-24 (Torres); Pl.'s Exh. 9 at EV 2014-1582, 1585, 1602.

22. A primary form of advertising for Evista takes place through in-person visits by Eli Lilly sales representatives to physicians. Tr. at 144 (Crenshaw); Tr. at 245-47 (Nicholson); Tr. at 857-59 (Torres). Sales representatives are an important source of information for physicians about prescription drugs, and physicians-who are the "gatekeepers" for patients, Tr. at 233-34 (Harenberg)-often rely to some extent on the information they are given by sales representatives in determining what drugs to prescribe. It is thus critical that sales representatives convey accurate and reliable information when detailing drugs to physicians. Tr. at 44-45 (Anson); Tr. at 166-68 (Crenshaw).

23. Eli Lilly has approximately one thousand primary case sales representatives. These representatives receive a base salary as well as a bonus based on the number of prescriptions for Eli Lilly drugs written by physicians they visit. The representatives detail an average of eight doctors per day, which translates into nearly 200 detail visits each month. Tr. at 147-49, 151 (Crenshaw); Tr. at 857 (Torres). The evidence suggests that each detail visit lasts an average of just two to three minutes. During those two to three minutes, representatives must detail several Eli Lilly drugs, not just Evista. Tr. at 798-99 (Torres).

24. Eli Lilly has several measures in place to ensure that its representatives convey authorized and intended messages to physicians and that they follow-up appropriately in subsequent visits. To that end, Eli Lilly provides its sales representatives with selling scripts or "verbatims" that tell them what to say to doctors about Evista either proactively or in response to questions from physicians. Tr. at 801-02 (Torres).

25. In addition, Eli Lilly representatives are trained and required to maintain written notes, prepared as soon as possible after each visit with a physician, encapsulating the visit. The purpose of these "call notes" is to provide an accurate record of what the sales representative and the doctor discussed and to record contemporaneously what the representative believes were the most salient aspects of each visit. Eli Lilly's Vice President of U.S. Sales, Newt Crenshaw, testified that the call notes are "utilized by that sales representative and/or their partner in the ongoing dialogue or promotional efforts with a given physician."Tr. at 154 (Crenshaw); *see also* Tr. at 152-60 (Crenshaw); Tr. at 877-78 (Torres). As contemporaneous written accounts, they are the best evidence of what the representatives communicated to doctors during their detail visits.

***9** 26. Eli Lilly also relies on market research to track the messages that its sales representatives are conveying to physicians. Tr. at 168 (Crenshaw). In the case of Evista, Eli Lilly commissioned a series of surveys conducted bimonthly throughout 1998 by a market research firm called Richard Day Research. Under Eli Lilly's guidance and direction, Richard Day periodically surveyed hundreds of physicians who had recently been detailed by an Evista sales representative and asked them among other things to describe the message the Eli Lilly representative had communicated about Evista. Tr. at 234-36 (Harenberg). According to John Ross, the Project Manager at Richard Day who together with Eli Lilly designed and conducted this survey, "one of the goals of the study [was] to get a sense of the message that was being delivered to those doctors from those reps and see if specific messages were being recalled by those doctors or not."Tr. at 519 (Ross).

27. The evidence adduced at the hearing demonstrates that since at least October 1998, Eli Lilly representatives have been communicating to physicians that Evista has been proven to reduce the risk of breast cancer and that Evista is comparable or superior to tamoxifen in reducing the risk of breast cancer. This evidence includes the following: (i) Eli Lilly's detail scripts distributed to sales representatives in November and December 1998, (ii) the sales representatives' call notes, (iii) the testimony of Eli Lilly business executives, (iv) eyewitness testimony, and (v) a Richard Day survey conducted in late November and early December 1998.

28. In mid-1998, even before tamoxifen had received an indication from the FDA for breast cancer risk reduction, Zeneca began receiving anecdotal reports that Eli Lilly was promoting Evista

for breast cancer prevention. In late May 1998, Zeneca's Chief Executive Officer wrote to Eli Lilly's president asking him to put a halt to any improper breast cancer promotion by the company's sales representatives. *See* Pl.'s Exh. 1 (Ltr. from T.F.W. McKillop to Sidney Taurel dated May 29, 1998). In June 1998, Eli Lilly's president denied Zeneca's accusations and communicated to Zeneca that any such claims by Eli Lilly sales representatives would be cause for "serious disciplinary action" by the company. His letter assured Zeneca that

> sales representatives have been instructed repeatedly and in no uncertain terms that they cannot promote Evista for the prevention of breast cancer. We regularly check promotional message recall with our customers through controlled market research, and breast cancer prevention has not been mentioned, as you would expect were our representatives promoting Evista for that use.

Pl.'s Exh. 2 (Ltr. from Sidney Taurel to T.F.W. McKillop dated June 3, 1998); Tr. at 54-59 (Anson).

29. Zeneca was reassured by the letter from Eli Lilly's president, concluding that Eli Lilly "took our issues very seriously" and responded "as you would expect them to behave as a major pharmaceutical company."Tr. at 59 (Anson). However, in late 1998, after the launch of the new indication for breast cancer prevention for Nolvadex, Zeneca gradually began to hear more and qualitatively broader anecdotal evidence that Eli Lilly representatives were making the claims in question. Zeneca also commissioned market research as part of its Nolvadex launch, and that research, particularly the studies completed in January 1999, provided more concrete proof that Eli Lilly's representatives were making breast cancer risk reduction claims. Tr. at 62-68 (Anson).

***10** 30. As set forth below, it appears that Eli Lilly began communicating two of the claims in question-that Evista has been proven to reduce the risk of breast cancer and that Evista is comparable or superior to tamoxifen in reducing the risk of breast cancer-in a systematic way in late 1998, when Eli Lilly issued new verbatim scripts for its sales representatives. However, there is insufficient evidence to conclude that Eli Lilly was communicating the third alleged claim-that Evista is approved or indicated by the FDA for reduction of the risk of breast cancer.

1. *The November and December 1998 detailing scripts*

31. Until November 1998, Eli Lilly had in place a verbatim script which stated only that recent data have shown that Evista "may also prevent breast cancer." Pl.'s Exh. 14 (Document re: Sales Representative Verbatim Response to Evista and Breast Cancer Prevention Questions dated May 14, 1998). This was part of a verbatim response that could be given to an unsolicited question by a doctor as to whether Evista prevented breast cancer. It was linked to the message that Evista prevented osteoporosis without increasing the risk of breast cancer. Shortly after Zeneca obtained the risk reduction indication for tamoxifen from the FDA, Eli Lilly revised its selling script for its sales representatives. Tr. at 867 (Torres); Pl.'s Exh. 15 (Document re: Questions comparing the ability of Evista and tamoxifen to prevent the incidence of newly diagnosed breast cancers dated Nov. 18, 1998). In an effort to position Evista as a drug that could also be used in the same way as tamoxifen, Eli Lilly told its representatives in November 1998 that in response to unsolicited questions from physicians concerning the comparative efficacy of the two drugs, Eli Lilly representatives should reply as follows:

> Dr., Evista is not approved for the prevention of breast cancer. However, let me share with you these data we currently have with regard to Evista reducing the incidence of breast cancer.
>
> Dr., these data come from about 13,000 women age 45-80 enrolled in our osteoporosis prevention and treatment studies. Women who have taken Evista for an average of 29 months had a greater than 50% reduction in the incidence of newly-diagnosed breast cancers compared with the placebo group. While we do not currently have head-to-head trials, *these results are similar to those for tamoxifen in women at high risk of breast cancer.*

Pl.'s Exh. 15 at EV 2609 327-28 (emphasis added). The script went on to promote the purported superior safety profile of Evista over tamoxifen: "

> Dr., a very distinct difference between Evista and tamoxifen lies in the uterine safety profile. In women, tamoxifen increases endometrial thickness, and increases the risk of polyps, and endometrial cancer. In contrast, Evista, does not increase

endometrial thickness or increase the risk of endometrial cancer."*Id.* at 328.

32. As Eli Lilly has acknowledged, without a head to head trial there is no scientific basis for drawing this comparison, particularly the statistical comparison of the efficacy of the two drugs in the same population. Tr. at 180 (Crenshaw); Tr. at 740 (Cummings). Indeed, Eli Lilly's Director of Oncology Business testified that he could think of no situation in which it would be appropriate for an Eli Lilly sales representative to compare tamoxifen to Evista. Tr. at 251 (Nicholson).

***11** 33. In December 1998, the FDA approved a change in the safety portion of Evista's label to include results of the MORE study with respect to breast cancer, which was a secondary endpoint of the MORE study. Tr. at 619 (Cummings); Tr. at 846 (Torres); Tr. at 914-16 (Eckert). The approved language in the new package insert stated that:

Among 7017 women randomized to raloxifene, there were 6 cases of invasive breast cancer per 14,605 person-years of follow-up (0.41 per 1000). Among 3368 women randomized to placebo there were 10 cases of invasive breast cancer per 6991 person-years of follow-up (1.43 per 1000).*The effectiveness of raloxifene in reducing the risk of breast cancer has not yet been established.*

Def.'s Exh. H (Evista Package Insert Revised as of Dec. 2, 1998) at 8 (emphasis added).[FN5]

FN5. The most recent data from the MORE study have shown 27 cases of invasive breast cancer in those women taking a placebo and 13 cases for those women taking raloxifene.

34. As a result of the label change, Eli Lilly gave its sales representatives a revised detailing script, which was distributed to the Evista sales force in mid-December. That detailing script instructs representatives to deliver the following message:

Dr., the FDA has recently approved a label (package insert) change for EVISTA regarding the incidence of newly diagnosed invasive breast cancer. ...

As you can see [from the package insert] this reflects a greater than 50% reduction in newly diagnosed breast cancer compared to placebo.

As a matter of fact, in our clinical trial of over 10,000 women of which 7,017 took EVISTA as compared to 3,368 who took placebo, there was a greater than 50% reduction in the incidence of newly diagnosed breast cancer.

Pl.'s Exh. 21 (Document re: Evista 3-year interim analysis from the Multiple Outcomes of Raloxifene Evaluation (MORE) study regarding fracture data and label change regarding breast cancer dated Dec. 11, 1998) at EV 2218 668. The sales script also provides that in the event physicians ask, "how can EVISTA show prevention of breast cancer with only 16 patients?" the appropriate response is that " 10 cases of invasive breast cancer were diagnosed in the placebo group and six were diagnosed in the Evista group" and "[t]his information translates to a greater than 50% reduction in breast cancer risk."*Id.* at 672; *see also* Pl.'s Exh. 67 at EV 205 77[5] (noting that in "Q4 '98," Eli Lilly "added proactive BC information" to its core message).

35. As part of the label change, the FDA required Eli Lilly to place on the label the following statement: "The effectiveness of raloxifene in reducing the risk of breast cancer has not yet been established."Def.'s Exh. H at 8. The December script instructed that, if representatives are asked what that sentence means, they should respond: " This is somewhat standard language included by the FDA to ensure that physicians understand that studies are ongoing and EVISTA is not indicated for the prevention of breast cancer."Pl.'s Exh. 21 at EV 2218 673. The plain language of the statement contradicts that interpretation.

2. *Eli Lilly sales representatives' call notes*

***12** 36. In light of these instructions, Eli Lilly sales representatives have repeatedly told physicians that Evista is a proven breast cancer prevention drug and a proven alternative to tamoxifen. Tr. at 230, 874-75 (Torres). From October 1998, when Nolvadex was first approved for breast cancer risk reduction, through March 1, 1999, after this suit was filed, call notes made by Eli Lilly sales representatives contain more than 500 entries in which Eli Lilly representatives report making